

ABX-PHRI CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application

Applicants : Abraham Pinter et al.
Application No. : 10/628,004 Confirmation No. 3975
Filed : July 25, 2003
For : USE OF TRANSGENIC MICE FOR THE
EFFICIENT ISOLATION OF NOVEL HUMAN
MONOCLONAL ANTIBODIES WITH
NEUTRALIZING ACTIVITY AGAINST PRIMARY
HIV-1 STRAINS AND NOVEL HIV-1
NEUTRALIZING ANTIBODIES
Group Art Unit : 1645
Examiner : Not Yet Assigned

New York, New York 10020
March 3, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR
INFORMATION DISCLOSURE STATEMENT

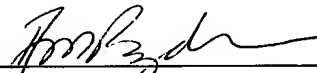
Sir:

Transmitted herewith is an Information Disclosure Statement in the
above-identified application. This Statement is submitted:

- ☐ within three months of the application filing date;
☒ more than three months from the application
filing date but before the mailing date of the first
Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

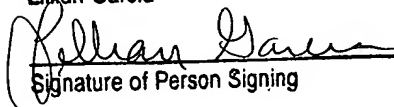


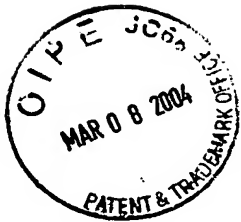
Jane T. Gunnison (Reg. No. 38,479)
Stanley D. Liang (Reg. No. 43,753)
Attorneys for Applicants
R. Minako Pazdera (Reg. No. 46,984)
Agent for Applicants

c/o FISH & NEAVE
Customer No. 1473
1251 Avenue of the Americas
New York, New York 10020-1104
Tel.: (212) 596-9000
Fax.: (212) 596-9090

I hereby certify that this
Correspondence is being
deposited with the U.S.
Postal Service as First
Class Mail in an envelope
Addressed to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450 on

March 3, 2004
Lillian Garcia


Signature of Person Signing



ABX-PHRI CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application

Applicants : Abraham Pinter et al.
Application No. : 10/628,004 Confirmation No. 3975
Filed : July 25, 2003
For : USE OF TRANSGENIC MICE FOR THE
EFFICIENT ISOLATION OF NOVEL HUMAN
MONOCLONAL ANTIBODIES WITH
NEUTRALIZING ACTIVITY AGAINST
PRIMARY HIV-1 STRAINS AND NOVEL HIV-1
NEUTRALIZING ANTIBODIES
Group Art Unit : 1645
Examiner : Not Yet Assigned

New York, New York 10020
March 3, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants make of record the
following documents:*

U.S. Patents

<u>Applicant</u>	<u>Patent No.</u>	<u>Issue Date</u>
Chang et al.	5,266,478	November 30, 1993

* A complete Form PTO-1449 listing these documents is attached hereto .

Foreign Publications

WO 95/24904	September 21, 1995
WO 96/34096	October 31, 1996
WO 99/12556	March 18, 1999

Other Documents

Alsmadi, O. et al., "Antibody-Dependent Cellular Cytotoxicity Directed against Cells Expressing Human Immunodeficiency Virus Type 1 Envelope of Primary or Laboratory-Adapted Strains by Human and Chimpanzee Monoclonal Antibodies of Different Epitope Specificities," *J. Virol.*, 72:286-293 (1998)

Arendrup, M. et al., "The HIV-1 V3 Domain on Field Isolates: Participation in Generation of Escape Virus In Vivo and Accessibility to Neutralizing Antibodies," *Arch Virol.*, 140:655-670 (1995)

Arendrup, M. et al., "Neutralizing Antibody Response During Human Immunodeficiency Virus Type 1 Infection: Type and Group Specificity and Viral Escape," *Journal of General Virology*, 74:855-863 (1993)

Barbas, C. F. et al., "Molecular Profile of an Antibody Response to HIV-1 as Probed by Combinatorial Libraries," *J. Mol. Biol.*, 230:812-823 (1993)

Berger, E.A. et al., "Chemokine Receptors As HIV-1 Coreceptors: Roles in Viral Entry, Tropism, and Disease," *Annual Reviews Immunol.*, 17:657-700 (1999).

Berman, P.W. et al., "Genetic and Immunologic Characterization of Viruses Infecting MN-rgp 120-Vaccinated Volunteers," *The Journal of Infectious Diseases*, 176:384-397 (1997)

Binley, J.M. et al., "An Investigation of the High-Avidity Antibody Response to Glycoprotein 120 of Human Immunodeficiency Virus Type 1," *AIDS Research and Human Retroviruses*, 13:1007-1015 (1997)

Boots, L.J. et al., "Anti-Human Immunodeficiency Virus Type 1 Human Monoclonal Antibodies that Bind Discontinuous Epitopes in the Viral Glycoproteins Can Identify Mimotopes from Recombinant Phage Peptide Display Libraries," *AIDS Research and Human Retroviruses*, 13:1549-1559 (1997)

Conley, A.J. et al., "Neutralization of Primary Human Immunodeficiency Virus Type 1 Isolates by the Broadly Reactive Anti-V3 Monoclonal Antibody, 447-52D," *J. Virol.*, 68:6994-7000 (1994)

Conley, A.J. et al., "Neutralization of Divergent Human Immunodeficiency Virus Type 1 Variants and Primary Isolates by IAM-41-2F5, an Anti-gp41 Human Monoclonal Antibody," *Proc. Natl. Acad. Sci.*, 91:3348-3352 (1994)

Ditzel, H.J. et al., "Mapping the Protein Surface of Human Immunodeficiency Virus Type 1 gp120 using Human Monoclonal Antibodies from Phage Display Libraries," *J. Mol. Biol.*, 267:684-695 (1997)

- D'Souza, P.M. et al., "Evaluation of Monoclonal Antibodies to HIV-1 by Neutralization and Serological Assays: an International Collaboration," *AIDS*, 5:1061-1070 (1991)
- D'Souza, P.M. et al., "Neutralization of Primary HIV-1 Isolates by Anti-Envelope Monoclonal Antibodies," *AIDS*, 9:867-874 (1995)
- D'Souza, P.M. et al., "Evaluation of Monoclonal Antibodies to Human Immunodeficiency Virus Type 1 Primary Isolates by Neutralization Assays: Performance Criteria for Selecting Candidate Antibodies for Clinical Trials," *The Journal of Infectious Diseases*, 175:1056-1062 (1997)
- Fontenot, J.D. et al., "Presentation of HIV V3 Loop Epitopes for Enhanced Antigenicity, Immunogenicity and Diagnostic Potential," *AIDS*, 9:1121-1129 (1995)
- Forthal, D.N. et al., "Functional Activities of 20 Human Immunodeficiency Virus Type 1 (HIV-1)-Specific Human Monoclonal Antibodies," *AIDS Research and Human Retroviruses*, 11:1095-1099 (1995)
- Fouts, T.R. et al., "Neutralization of the Human Immunodeficiency Virus Type 1 Primary Isolate JR-FL by Human Monoclonal Antibodies Correlates with Antibody Binding to the Oligomeric Form of the Envelope Glycoprotein Complex," *J. Virol.*, 71:2779-2785 (1997)
- Fung, M.S.C. et al., "Identification and Characterization of a Neutralization Site Within the Second Variable Region of Human Immunodeficiency Virus Type 1 gp120," *J. Virol.*, 66:848-856 (1992)
- Gauduin, M.-C. et al., "Effective Ex Vivo Neutralization of Human Immunodeficiency Virus Type 1 in Plasma by Recombinant Immunoglobulin Molecules," *J. Virol.*, 70:2586-2592 (1996)
- Gorny, M.K. et al., "Production of Site-Selected Neutralizing Human Monoclonal Antibodies against the Third Variable Domain of the Human Immunodeficiency Virus Type 1 Envelope Glycoprotein," *Proc. Natl. Acad. Sci.*, 88:3238-3242 (1991)
- Gorny, M.K. et al., "Repertoire of Neutralizing Human Monoclonal Antibodies Specific for the V3 Domain of HIV-1 gp120," *J. Immunol.*, 150:635-643 (1993)
- Gorny, M.K. et al., "Human Anti-V2 Monoclonal Antibody that Neutralizes Primary but not Laboratory Isolates of Human Immunodeficiency Virus Type 1," *J. Virol.*, 68:8312-8320 (1994)
- Gorny, M.K. et al., "Human Monoclonal Antibodies to the V3 Loop of HIV-1 With Intra- and Interclade Cross-Reactivity," *J. Immunol.*, 159:5114-5122 (1997)
- Gorny, M.K. et al., "A Human Monoclonal Antibody Specific for the V3 Loop of HIV Type 1 Clade E Cross-React with Other HIV Type 1 Clades," *AIDS Research and Human Retroviruses*, 14:213-221 (1998)

- He, Y. et al., "Efficient Isolation of Novel Human Monoclonal Antibodies with Neutralizing Activity Against HIV-1 from Transgenic Mice Expressing Human Ig Loci," *J. Immunol.*, 169:595-605 (2002)
- Hill, M.C. et al., "Envelope Glycoproteins from Human Immunodeficiency Virus Types 1 and 2 and Simian Immunodeficiency Virus Can Use Human CCR5 as a Coreceptor for Viral Entry and Make Direct CD4-Dependent Interactions with This Chemokine Receptor," *J. Virol.*, 71:6296-6304 (1997)
- Karwowska, S. et al., "'Type-Specific' Human Monoclonal Antibodies Cross-React with the V3 Loop of Various HIV-1 Isolates," *Vaccines* 92, 171-174 (1992)
- Kayman, S.C. et al., "Presentation of Native Epitopes in the V1/V2 and V3 Regions of Human Immunodeficiency Virus Type 1 gp120 by Fusion Glycoproteins Containing Isolated gp120 Domains," *J. Virol.*, 68:400-410 (1994)
- Krachmarov, C.P. et al., "V-3 Specific Polyclonal Antibodies Affinity Purified from Sera of Infected Humans Effectively Neutralize Primary Isolates of Human Immunodeficiency Virus Type 1," *AIDS Research and Human Retroviruses*, 17:1737-1748 (2001)
- LaCasse, R.A. et al., "Fusion-Competent Vaccines: Broad Neutralization of Primary Isolates of HIV," *Science*, 283:357-362 (1999)
- Laisney, I.L. et al., "Dual Specificity of a Human Neutralizing Monoclonal Antibody, Specific for the V3 Loop of GP120 (HIV-1)," *Immunology Letters*, 67:185-192 (1999)
- Little, M. et al., "Of Mice and Men: Hybridoma and Recombinant Antibodies," *Immunology Today*, 21:364-370 (2000)
- McKeating, J.A. et al., "Chimeric Viruses Expressing Primary Envelope Glycoproteins of Human Immunodeficiency Virus Type 1 Show Increased Sensitivity to Neutralization by Human Sera," *Virology*, 220:450-460 (1996)
- Mondor, I. et al., "Human Immunodeficiency Virus Type 1 Attachment to HeLa CD4 Cells Is CD4 Independent and gp120 Dependent and Requires Cell Surface Heparans," *J. Virol.*, 72:3623-3634 (1998)
- Moore, J.P. et al., "Immunochemical Analysis of the gp120 Surface Glycoprotein of Human Immunodeficiency Virus Type 1: Probing the Structure of the C4 and V4 Domains and the Interaction of the C4 Domain with the V3 Loop," *J. Virol.*, 67:4785-4796 (1993)
- Moore, J.P. et al., "Probing the Structure of the V2 Domain of Human Immunodeficiency Virus Type 1 Surface Glycoprotein gp120 with a Panel of Eight Monoclonal Antibodies: Human Immune Response to the V1 and V2 Domains," *J. Virol.*, 67:6136-6151 (1993)
- Moore, J.P. et al., "Development of the Anti-gp120 Antibody Response During Seroconversion to Human Immunodeficiency Virus Type 1," *J. Virol.*, 68:5142-5155 (1994)

- Moore, J.P. et al., "Exploration of Antigenic Variation in gp120 From Clades A Through F of Human Immunodeficiency Virus Type 1 by Using Monoclonal Antibodies," *J. Virol.*, 68:8350-8364 (1994)
- Moore, J.P. et al., "HIV-1 Neutralization: the Consequence of Viral Adaptation to Growth on Transformed T Cells," *AIDS*, 9:S117-S136 (1995)
- Moore, J.P. et al., "A Human Monoclonal Antibody to a Complex Epitope in the V3 Region of gp120 of Human Immunodeficiency Virus Type 1 Has Broad Reactivity Within and Outside Clade B," *J. Virol.*, 69:122-130 (1995)
- Moore, J.P. et al., "Antibody Cross-Competition Analysis of the Human Immunodeficiency Virus Type 1 gp120 Exterior Envelope Glycoprotein," *J. Virol.*, 70:1863-1872 (1996)
- Murakami, T. et al., "Inhibitory Mechanism of the CXCR4 Antagonist T22 against Human Immunodeficiency Virus Type 1 Infection," *J. Virol.*, 73:7489-7496 (1999)
- Nyambi, P.N. et al., "Mapping of Epitopes Exposed on Intact Human Immunodeficiency Virus Type 1 (HIV-1) Virions: a New Strategy for Studying the Immunologic Relatedness of HIV-1," *J. Virol.*, 72:9384-9391 (1998)
- Pal, R. et al., "Characterization of a Neutralizing Monoclonal Antibody to the External Glycoprotein of HIV-1," *Intervirology*, 86:86-93 (1992)
- Parren, P.W. H. et al., "Antibodies against HIV-1 from Phage Display Libraries: Mapping of an Immune Response and Progress Towards Antiviral Immunotherapy," *Chemical Immunology*, 65:18-56 (1997)
- Parren, P.W. H. et al., "Erratum to 'Relevance of the Antibody Response Against Human Immunodeficiency Virus Type 1 Envelope to Vaccine Design'," *Immunology Letters*, 58:125-132 (1997)
- Parren, P.W. H. et al., "Neutralization of Human Immunodeficiency Virus Type 1 by Antibody to gp120 Is Determined Primarily by Occupancy of Sites on the Virion Irrespective of Epitope Specificity," *J. Virol.*, 72:3512-3519 (1998)
- Pinter, A. et al., "A Potent, Neutralizing Human Monoclonal Antibody Against a Unique Epitope Overlapping the CD4 Binding Site of HIV-1 gp120 That is Broadly Conserved Across North American and African Virus Isolates," *AIDS Research and Human Retroviruses*, 9:985-996 (1993)
- Pinter, A. et al., "Potent Neutralization of Primary HIV-1 Isolates by Antibodies Directed Against Epitopes Present in the V1/V2 Domain of HIV-1 gp120," *Vaccine*, 16:1803-1811 (1998)
- Robinson, J.E. et al., "Identification of Conserved and Variant Epitopes of Human Immunodeficiency Virus Type 1 (HIV-1) gp120 by Human Monoclonal Antibodies Produced by EBV-Transformed Cell Lines," *AIDS Research and Human Retroviruses*, 6:567-579 (1990)

Sattentau, Q.J., "Conservation of HIV-1 gp120 Neutralizing Epitopes After Formalin Inactivation," *AIDS*, 9:1383-1385 (1995)

Schnierle, B.S. et al., "Pseudotyping of Murine Leukemia Virus with the Envelope Glycoproteins of HIV Generates a Retroviral Vector with Specificity of Infection for CD4-Expressing Cells," *Proc. Natl. Acad. Sci.*, 94:8640-8645 (1997)

Schutten, M. et al., "Characterization of a V3 Domain-Specific Neutralizing Human Monoclonal Antibody that Preferentially Recognizes Non-Syncytium-Inducing Human Immunodeficiency Virus Type 1 Strains," *Journal of General Virology*, 76:1665-1673 (1995)

Schutten, M. et al., "Enhancement of Infectivity of a Non-Syncytium Inducing HIV-1 by sCD4 and by Human Antibodies that Neutralize Syncytium-Inducing HIV-1," *Scand. J. Immunol.*, 41:18-22 (1995)

Schutten, M. et al., "Human Antibodies that Neutralize Primary Human Immunodeficiency Virus Type 1 *in vitro* Do Not Provide Protection in an *in vivo* Model," *Journal of General Virology*, 77:1667-1675 (1996)

Schutten, M. et al., "Modulation of Primary Human Immunodeficiency Virus Type 1 Envelope Glycoprotein-Mediated Entry by Human Antibodies," *Journal of General Virology*, 78:999-1006 (1997)

Scott, C.F. et al., "Human Monoclonal Antibody That Recognizes the V3 Region of Human Immunodeficiency Virus gp120 and Neutralizes the Human T-Lymphotropic Virus Type III_{MN} Strain," *Proc. Natl. Acad. Sci.*, 87:8597-8601 (1990)

Seligman, S.J. et al., "Characterization by Serial Deletion Competition ELISAs of HIV-1 V3 Loop Epitopes Recognized by Monoclonal Antibodies," *Molecular Immunology*, 33:737-745 (1996)

Stamatatos, L. et al., "An Envelope Modification That Renders a Primary, Neutralization-Resistant Clade B Human Immunodeficiency Virus Type 1 Isolate Highly Susceptible to Neutralization by Sera from Other Clades," *J. Virol.*, 72:7840-7845 (1998)

Sullivan, N. et al., "Determinants of Human Immunodeficiency Virus Type 1 Envelope Glycoprotein Activation by Soluble CD4 and Monoclonal Antibodies," *J. Virol.*, 72:6332-6338 (1998)

Thall, M. et al., "Characterization of Conserved Human Immunodeficiency Virus Type 1 gp120 Neutralization Epitopes Exposed Upon gp120-CD4 Binding," *J. Virol.*, 67:3978-3988 (1993)

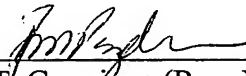
Tilley, S.A. et al., "Synergistic Neutralization of HIV-1 by Human Monoclonal Antibodies Against the V3 Loop and the CD4-Binding Site of gp120," *AIDS Research and Human Retroviruses*, 8:461-467 (1992)

Trkola, A. et al., "Cross-Clade Neutralization of Primary Isolates of Human Immunodeficiency Virus Type 1 by Human Monoclonal Antibodies and Tetrameric CD4-IgG," *J. Virol.*, 69:6609-6617 (1995)

- Trkola, A. et al., "CD4-Dependent, Antibody-Sensitive Interactions Between HIV-1 and Its Co-receptor CCR-5," *Nature*, 384:184-187 (1996)
- Trkola, A. et al., "Human Monoclonal Antibody 2G12 Defines a Distinctive Neutralization Epitope on the gp120 Glycoprotein of Human Immunodeficiency Virus Type 1," *J. Virol.*, 70:1100-1108 (1996)
- Tykola, A. et al., "Neutralization Sensitivity of Human Immunodeficiency Virus Type 1 Primary Isolates to Antibodies and CD4-Based Reagents Is Independent of Coreceptor Usage," *J. Virol.*, 72:1876-1885 (1998)
- Ugolini, S. et al., "Inhibition of Virus Attachment to CD4⁺ Target Cells Is a Major Mechanism of T Cell Line-Adapted HIV-1 Neutralization," *J. Exp. Med.*, 186:1287-1298 (1997)
- VanCott, T.C. et al., "Dissociation Rate of Antibody-gp120 Binding Interactions Is Predictive of V3-Mediated Neutralization of HIV-1," *J. Immunol.*, 153:449-459 (1994)
- van Sriel, A.B., "Immunotherapeutic Perspective for Bispecific Antibodies," *Immunology Today*, 21:391-397 (2000).
- Wu, D. et al., "Neuroprotection With Noninvasive Neurotrophin Delivery to the Brain," *Proc. Natl. Acad. Sci. USA*, 96:254-259 (1999).
- Wu, L. et al., "CD4-Induced Interaction of Primary HIV-1 gp120 Glycoproteins With the Chemokine Receptor CCR-5," *Nature*, 384:179-183 (1996)
- Yang, G. et al., "Neutralizing Antibodies Against HIV Determined by Amplification of Viral Long Terminal Repeat Sequences From Cells Infected in Vitro by Nonneutralized Virions," *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, 17:27-34 (1998)
- Zolla-Pazner, S. et al., "Neutralization of a Clade B Primary Isolate by Sera from Human Immunodeficiency Virus —Uninfected Recipients of Candidate AIDS Vaccines," *J. Infect. Diseases.*, 175:764-774 (1997)
- Zolla-Pazner, S. et al., "Immunotyping of Human Immunodeficiency Virus Type 1 (HIV): an Approach to Immunologic Classification of HIV," *J. Virol.*, 73:4042-4051 (1999)

Applicants respectfully request that the above documents be (1) fully considered by the Examiner during the course of the examination of this application and (2) printed on any patent issuing from this application. Applicants also request that a copy of the enclosed Form PTO-1449 duly initialed by the Examiner be forwarded to the undersigned with the next communication.

Respectfully submitted,

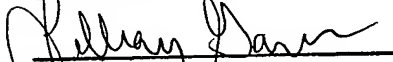


Jane T. Gunnison (Reg. No. 38,479)
Stanley D. Liang (Reg. No. 43,753)
Attorneys for Applicants
R. Minako Pazdera (Reg. No. 46,984)
Agent for Applicants
c/o Fish & Neave
Customer No. 1473
1251 Avenue of the Americas
New York, New York 10020-1104
Tel.: (212) 596-9000
Fax: (212) 596-9090

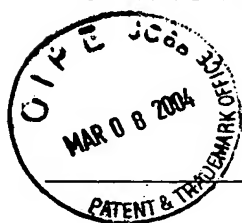
I hereby certify that this
Correspondence is being
deposited with the U.S.
Postal Service as First
Class Mail in an envelope
Addressed to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450 on

March 3, 2004

Lillian Garcia


Signature of Person Signing

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
ABX-PHRI CONAPPLN. NO.
10/628,004INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Abraham Pinter et al.CONFIRMATION NO.
3975FILING DATE
July 25, 2003GROUP
1645

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,266,478	11/30/1993	Chang et al.	435	240.27	

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 95/24904	09/21/1995	PCT				
	WO 96/34096	10/31/1996	PCT				
	WO 99/12556	3/18/1999	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

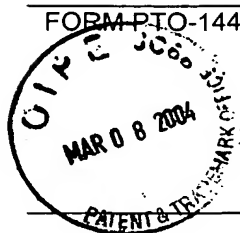
EXAMINER INITIAL	
	Alsmadi, O. et al., "Antibody-Dependent Cellular Cytotoxicity Directed against Cells Expressing Human Immunodeficiency Virus Type 1 Envelope of Primary or Laboratory-Adapted Strains by Human and Chimpanzee Monoclonal Antibodies of Different Epitope Specificities," <i>J. Virol.</i> , 72:286-293 (1998)
	Arendrup, M. et al., "The HIV-1 V3 Domain on Field Isolates: Participation in Generation of Escape Virus In Vivo and Accessibility to Neutralizing Antibodies," <i>Arch Virol</i> , 140:655-670 (1995)
	Arendrup, M. et al., "Neutralizing Antibody Response During Human Immunodeficiency Virus Type 1 Infection: Type and Group Specificity and Viral Escape," <i>Journal of General Virology</i> , 74:855-863 (1993)
	Barbas, C.F. et al., "Molecular Profile of an Antibody Response to HIV-1 as Probed by Combinatorial Libraries," <i>J. Mol. Biol.</i> , 230:812-823 (1993)
	Berger, E.A. et al., "Chemokine Receptors As HIV-1 Coreceptors: Roles in Viral Entry, Tropism, and Disease," <i>Annual Reviews Immunol.</i> , 17:657-700 (1999).
	Berman, P.W. et al., "Genetic and Immunologic Characterization of Viruses Infecting MN-rgp 120-Vaccinated Volunteers," <i>The Journal of Infectious Diseases</i> , 176:384-397 (1997)
	Binley, J.M. et al., "An Investigation of the High-Avidity Antibody Response to Glycoprotein 120 of Human Immunodeficiency Virus Type 1," <i>AIDS Research and Human Retroviruses</i> , 13:1007-1015 (1997)
	Boots, L.J. et al., "Anti-Human Immunodeficiency Virus Type 1 Human Monoclonal Antibodies that Bind Discontinuous Epitopes in the Viral Glycoproteins Can Identify Mimotopes from Recombinant Phage Peptide Display Libraries," <i>AIDS Research and Human Retroviruses</i> , 13:1549-1559 (1997)
	Conley, A.J. et al., "Neutralization of Primary Human Immunodeficiency Virus Type 1 Isolates by the Broadly Reactive Anti-V3 Monoclonal Antibody, 447-52D," <i>J. Virol.</i> , 68:6994-7000 (1994)
	Conley, A.J. et al., "Neutralization of Divergent Human Immunodeficiency Virus Type 1 Variants and Primary Isolates by IAM-41-2F5, an Anti-gp41 Human Monoclonal Antibody," <i>Proc. Natl. Acad. Sci.</i> , 91:3348-3352 (1994)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449


U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
ABX-PHRI CONAPPLN. NO.
10/628,004INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Abraham Pinter et al.CONFIRMATION NO.
3975FILING DATE
July 25, 2003GROUP
1645

	Ditzel, H.J. et al., "Mapping the Protein Surface of Human Immunodeficiency Virus Type 1 gp120 using Human Monoclonal Antibodies from Phage Display Libraries," <i>J. Mol. Biol.</i> , 267:684-695 (1997).
	D'Souza, P.M. et al., "Evaluation of Monoclonal Antibodies to HIV-1 by Neutralization and Serological Assays: an International Collaboration," <i>AIDS</i> , 5:1061-1070 (1991)
	D'Souza, P.M. et al., "Neutralization of Primary HIV-1 Isolates by Anti-Envelope Monoclonal Antibodies," <i>AIDS</i> , 9:867-874 (1995)
	D'Souza, P.M. et al., "Evaluation of Monoclonal Antibodies to Human Immunodeficiency Virus Type 1 Primary Isolates by Neutralization Assays: Performance Criteria for Selecting Candidate Antibodies for Clinical Trials," <i>The Journal of Infectious Diseases</i> , 175:1056-1062 (1997)
	Fontenot, J.D. et al., "Presentation of HIV V3 Loop Epitopes for Enhanced Antigenicity, Immunogenicity and Diagnostic Potential," <i>AIDS</i> , 9:1121-1129 (1995)
	Forthal, D.N. et al., "Functional Activities of 20 Human Immunodeficiency Virus Type 1 (HIV-1)-Specific Human Monoclonal Antibodies," <i>AIDS Research and Human Retroviruses</i> , 11:1095-1099 (1995)
	Fouts, T.R. et al., "Neutralization of the Human Immunodeficiency Virus Type 1 Primary Isolate JR-FL by Human Monoclonal Antibodies Correlates with Antibody Binding to the Oligomeric Form of the Envelope Glycoprotein Complex," <i>J. Virol.</i> , 71:2779-2785 (1997)
	Fung, M.S. C. et al., "Identification and Characterization of a Neutralization Site Within the Second Variable Region of Human Immunodeficiency Virus Type 1 gp120," <i>J. Virol.</i> , 66:848-856 (1992)
	Gauduin, M.-C. et al., "Effective Ex Vivo Neutralization of Human Immunodeficiency Virus Type 1 in Plasma by Recombinant Immunoglobulin Molecules," <i>J. Virol.</i> , 70:2586-2592 (1996)
	Gorny, M.K. et al., "Production of Site-Selected Neutralizing Human Monoclonal Antibodies against the Third Variable Domain of the Human Immunodeficiency Virus Type 1 Envelope Glycoprotein," <i>Proc. Natl. Acad. Sci.</i> , 88:3238-3242 (1991)
	Gorny, M. K. et al., "Repertoire of Neutralizing Human Monoclonal Antibodies Specific for the V3 Domain of HIV-1 gp120," <i>J. Immunol.</i> , 150:635-643 (1993)
	Gorny, M.K. et al., "Human Anti-V2 Monoclonal Antibody that Neutralizes Primary but not Laboratory Isolates of Human Immunodeficiency Virus Type 1," <i>J. Virol.</i> , 68:8312-8320 (1994)
	Gorny, M.K., "Human Monoclonal Antibodies to the V3 Loop of HIV-1 With Intra- and Interclade Cross-Reactivity," <i>J. Immunol.</i> , 159: 5114-5122 (1997).
	Gorny, M.K. et al., "A Human Monoclonal Antibody Specific for the V3 Loop of HIV Type 1 Clade E Cross-React with Other HIV Type 1 Clades," <i>AIDS Research and Human Retroviruses</i> , 14:213-221 (1998).
	He, Y. et al., "Efficient Isolation of Novel Human Monoclonal Antibodies with Neutralizing Activity Against HIV-1 from Transgenic Mice Expressing Human Ig Loci," <i>J. Immunol.</i> , 169:595-605 (2002).
	Hill, M.C. et al., "Envelope Glycoproteins from Human Immunodeficiency Virus Types 1 and 2 and Simian Immunodeficiency Virus Can Use Human CCR5 as a Coreceptor for Viral Entry and Make Direct CD4-Dependent Interactions with This Chemokine Receptor," <i>J. Virol.</i> , 71:6296-6304 (1997)
	Karwowska, S. et al., "'Type-Specific' Human Monoclonal Antibodies Cross-React with the V3 Loop of Various HIV-1 Isolates," <i>Vaccines</i> 92, 171-174 (1992)
	Kayman, S.C. et al., "Presentation of Native Epitopes in the V1/V2 and V3 Regions of Human Immunodeficiency Virus Type 1 gp120 by Fusion Glycoproteins Containing Isolated gp120 Domains," <i>J. Virol.</i> , 68:400-410 (1994).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

	FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. ABX-PHRI CON	APPLN. NO. 10/628,004
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT Abraham Pinter et al.	CONFIRMATION NO. 3975
			FILING DATE July 25, 2003	GROUP 1645

	Krachmarov, C.P. et al., "V-3 Specific Polyclonal Antibodies Affinity Purified from Sera of Infected Humans Effectively Neutralize Primary Isolates of Human Immunodeficiency Virus Type 1," <i>AIDS Research and Human Retroviruses</i> , 17:1737-1748 (2001).
	LaCasse, R.A. et al., "Fusion-Competent Vaccines: Broad Neutralization of Primary Isolates of HIV," <i>Science</i> , 283:357-362 (1999)
	Laisney, I.L. et al., "Dual Specificity of a Human Neutralizing Monoclonal Antibody, Specific for the V3 Loop of GP120 (HIV-1)," <i>Immunology Letters</i> , 67:185-192 (1999)
	Little, M. et al., "Of Mice and Men: Hybridoma and Recombinant Antibodies," <i>Immunology Today</i> , 21:364-370 (2000).
	McKeating, J.A. et al., "Chimeric Viruses Expressing Primary Envelope Glycoproteins of Human Immunodeficiency Virus Type 1 Show Increased Sensitivity to Neutralization by Human Sera," <i>Virology</i> , 220:450-460 (1996)
	Mondor, I. et al., "Human Immunodeficiency Virus Type 1 Attachment to HeLa CD4 Cells Is CD4 Independent and gp120 Dependent and Requires Cell Surface Heparans," <i>J. Virol.</i> , 72:3623-3634 (1998)
	Moore, J.P. et al., "Immunochemical Analysis of the gp120 Surface Glycoprotein of Human Immunodeficiency Virus Type 1: Probing the Structure of the C4 and V4 Domains and the Interaction of the C4 Domain with the V3 Loop," <i>J. Virol.</i> , 67:4785-4796 (1993)
	Moore, J.P. et al., "Probing the Structure of the V2 Domain of Human Immunodeficiency Virus Type 1 Surface Glycoprotein gp120 with a Panel of Eight Monoclonal Antibodies: Human Immune Response to the V1 and V2 Domains," <i>J. Virol.</i> , 67:6136-6151 (1993)
	Moore, J.P. et al., "Development of the Anti-gp120 Antibody Response During Seroconversion to Human Immunodeficiency Virus Type 1," <i>J. Virol.</i> , 68:5142-5155 (1994)
	Moore, J.P. et al., "Exploration of Antigenic Variation in gp120 From Clades A Through F of Human Immunodeficiency Virus Type 1 by Using Monoclonal Antibodies," <i>J. Virol.</i> , 68:8350-8364 (1994)
	Moore, J.P. et al., "HIV-1 Neutralization: the Consequence of Viral Adaptation to Growth on Transformed T Cells," <i>AIDS</i> , 9:S117-S136 (1995)
	Moore, J.P. et al., "A Human Monoclonal Antibody to a Complex Epitope in the V3 Region of gp120 of Human Immunodeficiency Virus Type 1 Has Broad Reactivity Within and Outside Clade B," <i>J. Virol.</i> , 69:122-130 (1995)
	Moore, John P. et al., "Antibody Cross-Competition Analysis of the Human Immunodeficiency Virus Type 1 gp120 Exterior Envelope Glycoprotein," <i>J. Virol.</i> , 70:1863-1872 (1996)
	Murakami, T. et al., "Inhibitory Mechanism of the CXCR4 Antagonist T22 against Human Immunodeficiency Virus Type 1 Infection," <i>J. Virol.</i> , 73:7489-7496 (1999)
	Nyambi, P.N. et al., "Mapping of Epitopes Exposed on Intact Human Immunodeficiency Virus Type 1 (HIV-1) Virions: a New Strategy for Studying the Immunologic Relatedness of HIV-1," <i>J. Virol.</i> , 72:9384-9391 (1998)
	Pal, R. et al., "Characterization of a Neutralizing Monoclonal Antibody to the External Glycoprotein of HIV-1," <i>Intervirology</i> , 86:86-93 (1992)
	Parren, P.W. H. et al., "Antibodies against HIV-1 from Phage Display Libraries: Mapping of an Immune Response and Progress Towards Antiviral Immunotherapy," <i>Chemical Immunology</i> , 65:18-56 (1997)
	Parren, P.W. H. et al., "Erratum to 'Relevance of the Antibody Response Against Human Immunodeficiency Virus Type 1 Envelope to Vaccine Design'," <i>Immunology Letters</i> , 58:125-132 (1997)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
ABX-PHRI CONAPPLN. NO.
10/628,004INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Abraham Pinter et al.CONFIRMATION NO.
3975FILING DATE
July 25, 2003GROUP
1645

Parren, P.W. H. et al., "Neutralization of Human Immunodeficiency Virus Type 1 by Antibody to gp120 Is Determined Primarily by Occupancy of Sites on the Virion Irrespective of Epitope Specificity," *J. Virol.*, 72:3512-3519 (1998)

Pinter, A. et al., "A Potent, Neutralizing Human Monoclonal Antibody Against a Unique Epitope Overlapping the CD4 Binding Site of HIV-1 gp120 That is Broadly Conserved Across North American and African Virus Isolates," *AIDS Research and Human Retroviruses*, 9:985-996 (1993)

Pinter, A. et al., "Potent Neutralization of Primary HIV-1 Isolates by Antibodies Directed Against Epitopes Present in the V1/V2 Domain of HIV-1 gp120," *Vaccine*, 16:1803-1811 (1998).

Robinson, J.E. et al., "Identification of Conserved and Variant Epitopes of Human Immunodeficiency Virus Type 1 (HIV-1) gp120 by Human Monoclonal Antibodies Produced by EBV-Transformed Cell Lines," *AIDS Research and Human Retroviruses*, 6:567-579 (1990)

Sattentau, Q.J., "Conservation of HIV-1 gp120 Neutralizing Epitopes After Formalin Inactivation," *AIDS*, 9:1383-1385 (1995)

Schnierle, B.S. et al., "Psuedotyping of Murine Leukemia Virus with the Envelope Glycoproteins of HIV Generates a Retroviral Vector with Specificity of Infection for CD4-Expressing Cells," *Proc. Natl. Acad. Sci.*, 94:8640-8645 (1997)

Schutten, M. et al., "Characterization of a V3 Domain-Specific Neutralizing Human Monoclonal Antibody that Preferentially Recognizes Non-Syncytium-Inducing Human Immunodeficiency Virus Type 1 Strains," *Journal of General Virology*, 76:1665-1673 (1995)

Schutten, M. et al., "Enhancement of Infectivity of a Non-Syncytium Inducing HIV-1 by sCD4 and by Human Antibodies that Neutralize Syncytium-Inducing HIV-1," *Scand. J. Immunol.*, 41:18-22 (1995)

Schutten, M. et al., "Human Antibodies that Neutralize Primary Human Immunodeficiency Virus Type 1 *in vitro* Do Not Provide Protection in an *in vivo* Model," *Journal of General Virology*, 77:1667-1675 (1996)

Schutten, M. et al., "Modulation of Primary Human Immunodeficiency Virus Type 1 Envelope Glycoprotein-Mediated Entry by Human Antibodies," *Journal of General Virology*, 78:999-1006 (1997)

Scott, C.F. et al., "Human Monoclonal Antibody That Recognizes the V3 Region of Human Immunodeficiency Virus gp120 and Neutralizes the Human T-Lymphotropic Virus Type III_{MN} Strain," *Proc. Natl. Acad. Sci.*, 87:8597-8601 (1990)

Seligman, S.J. et al., "Characterization by Serial Deletion Competition ELISAs of HIV-1 V3 Loop Epitopes Recognized by Monoclonal Antibodies," *Molecular Immunology*, 33:737-745 (1996)

Stamatatos, L. et al., "An Envelope Modification That Renders a Primary, Neutralization-Resistant Clade B Human Immunodeficiency Virus Type 1 Isolate Highly Susceptible to Neutralization by Sera from Other Clades," *J. Virol.*, 72:7840-7845 (1998)

Sullivan, N. et al., "Determinants of Human Immunodeficiency Virus Type 1 Envelope Glycoprotein Activation by Soluble CD4 and Monoclonal Antibodies," *J. Virol.*, 72:6332-6338 (1998)

Thall, M. et al., "Characterization of Conserved Human Immunodeficiency Virus Type 1 gp120 Neutralization Epitopes Exposed Upon gp120-CD4 Binding," *J. Virol.*, 67:3978-3988 (1993)

Tilley, S.A. et al., "Synergistic Neutralization of HIV-1 by Human Monoclonal Antibodies Against the V3 Loop and the CD4-Binding Site of gp120," *AIDS Research and Human Retroviruses*, 8:461-467 (1992).

Trkola, A. et al., "Cross-Clade Neutralization of Primary Isolates of Human Immunodeficiency Virus Type 1 by Human Monoclonal Antibodies and Tetrameric CD4-IgG," *J. Virol.*, 69:6609-6617 (1995)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
ABX-PHRI CONAPPLN. NO.
10/628,004APPLICANT
Abraham Pinter et al.CONFIRMATION NO.
3975FILING DATE
July 25, 2003GROUP
1645INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Trkola, A. et al., "CD4-Dependent, Antibody-Sensitive Interactions Between HIV-1 and Its Co-receptor CCR-5," *Nature*, 384:184-187 (1996)

Trkola, A. et al., "Human Monoclonal Antibody 2G12 Defines a Distinctive Neutralization Epitope on the gp120 Glycoprotein of Human Immunodeficiency Virus Type 1," *J. Virol.*, 70:1100-1108 (1996)

Tykola, A. et al., "Neutralization Sensitivity of Human Immunodeficiency Virus Type 1 Primary Isolates to Antibodies and CD4-Based Reagents Is Independent of Coreceptor Usage," *J. Virol.*, 72:1876-1885 (1998)

Ugolini, S. et al., "Inhibition of Virus Attachment to CD4⁺ Target Cells Is a Major Mechanism of T Cell Line-Adapted HIV-1 Neutralization," *J. Exp. Med.*, 186:1287-1298 (1997)

VanCott, T.C. et al., "Dissociation Rate of Antibody-gp120 Binding Interactions Is Predictive of V3-Mediated Neutralization of HIV-1," *J. Immunol.*, 153:449-459 (1994)

van Spriël, A.B., "Immunotherapeutic Perspective for Bispecific Antibodies," *Immunology Today*, 21:391-397 (2000).

Wu, D. et al., "Neuroprotection With Noninvasive Neurotrophin Delivery to the Brain," *Proc. Natl. Acad. Sci.*, 96:254-259 (1999).

Wu, L. et al., "CD4-Induced Interaction of Primary HIV-1 gp120 Glycoproteins With the Chemokine Receptor CCR-5," *Nature*, 384:179-183 (1996)

Yang, G. et al., "Neutralizing Antibodies Against HIV Determined by Amplification of Viral Long Terminal Repeat Sequences From Cells Infected In Vitro by Nonneutralized Virions," *Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology*, 17:27-34 (1998)

Zolla-Pazner, S. et al., "Neutralization of a Clade B Primary Isolate by Sera from Human Immunodeficiency Virus —Uninfected Recipients of Candidate AIDS Vaccines," *J. Infect. Diseases.*, 175:764-774 (1997)

Zolla-Pazner, S. et al., "Immunotyping of Human Immunodeficiency Virus Type 1 (HIV): an Approach to Immunologic Classification of HIV," *J. Virol.*, 73:4042-4051 (1999)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not conformance and not considered. Include copy of this form with next communication to applicant.